NOV 7 2012

510(k) Summary – K112877

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. 510(k) Applicant Information:

Name: Shenzhen Comen Medical Instruments Co., Ltd.

Address: South of Floor 7, Block 5 & Floor 6, Block 4, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, Guangdong, 518052, P.R. China

Phone: 86-755-26431236 Fax: 86-755-26431232

Contact: Henry Duan Title: Regulations Manager

Date Submitted: 10/18/2012

2. Device Name:

Trade Name:	COMEN Multi-Parameter Patient Monitor C50, C60 and C80
Common Name:	Monitor, Physiological, Patient
Device Classification:	Class II
Classification Reference:	21 CFR 870.2300, Cardiac monitor (including cardiotachometer and rate alarm)
Product Code:	MWI

3. Predicate Device:

The legally marketed devices to which the submitter claims equivalence:

Goldway UT4000F Patient Monitor (K021154)
Goldway UT4000A Vital Signs Monitor (K033988)
VS-800 Vital Signs Monitor (K060281)
PM-9000 Express Patient Monitor (K070791)
OxiMax N-560 Pulse Oximeter (K021090)

4. Device Description:

COMEN Multi-Parameter Patient Monitor Models C50, C60 and C80 obtain and display physiological data of the patient including waveforms and numerical data in real time. COMEN C series can be custom configured to monitor electrocardiograph (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO2), respiration (RESP) or temperature (TEMP). These physiological signals are converted into digital data and displayed.

For each parameter, COMEN C series examine the data for alarm conditions and present them on the display. COMEN C series have audio alarming function that may raise the user's attention of system error or as dictated by the physiological parameter settings.

COMEN C series are capable of storing data trends for retrospective review and sending serial port signal to printer for report printing.

5. Intended Use:

Comen Multi-Parameter Patient Monitor models C50, C60, C80 are intended to monitor basic physiological parameters of patients within any professional medical environment. The user, responsible for interpreting the monitored data made available, will be a licensed healthcare practitioner. Physiological data, system alarms, and patient data will be made available to the user from the monitor.

The monitor models monitor parameters such as ECG (3-lead, 5-lead), Respiration (RESP), pulse oximetry (SpO2), noninvasive blood pressure (NIBP) and surface body and rectal temperature (TEMP) only. The models are equipped with alarms that indicate system faults, physiological parameters that have exceeded the limits set by the operator, or both.

The monitor models do not measure, display or trend changes in the ST segment, do not detect arrhythmia or provide arrhythmia alarm, and is not intended for use as an apnea monitor. The models are not intended for use during MRI or CT scans.

The monitor models are not designed for home use, and are restricted to be used on one patient at a time.

6. Predicate Devices:

The Substantial Equivalence of the subject device of this 510(k) notification COMEN C series (the "subject devices"), is claimed to Goldway UT4000F Patient Monitor, Goldway UT4000A Vital Signs Monitor, PM-9000 Express Patient Monitor, VS-800 Vital Signs Monitor, and OxiMax N-560 Pulse Oximeter (the "predicate devices").

The subject devices are Substantially Equivalent (SE) to the predicate devices with respect of effectiveness and safety.

7. Discussion on Non-Clinical Tests Performed:

COMEN C series meet the following standards:

IEC 60601-1-2
IEC 60601-2-30
IEC 60601-2-27
EN1060-1
EN1060-3
EN1060-4
EN60601-2-49
EN 60601-1
AAMI EC13
ISO10993-1
ASTM E1112-00
ISO 9919
ISO 80601-2-56

A risk analysis of the system and its software was performed and testing was conducted to validate the systems overall operation.

8. Discussion on Clinical Tests Performed:

Not Applicable

9. Conclusion:

COMEN Multi-Parameter Patient Monitor Models C50, C60 and C80 are substantially equivalent to, and as safe, as effective as, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 7 2012

Shenzhen Comen Medical Instruments Co., Ltd.
c/o Mr. Jimmy Wu
Lee & Xiao
2600 Mission St., Suite 100
San Marino, CA 91108

Re: K112877
Trade/Device Name: Comen Multi-Parameter Patient Monitor, Model C50, C60, and C80
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Product Code: MWI, DPS, DXN, DQA, FLL
Dated: October 18, 2012
Received: October 23, 2012

Dear Mr. Wu :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112877

Device Name: Comen Multi-Parameter Patient Monitor Models C50, C60, C80

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112877